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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,410	12/28/2000	Keiko Neriishi	030662-066	5255

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/749,410	Neriishi
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Mar 17, 2003* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *Mar 17, 2003* . Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached sheet.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: _____

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .

10. ☐ Other:

Claims 1-3 are rejected under 35 U.S.C. 103(a). over Some et al. (U.S. Patent 6,256,405 B1) (July 3, 2001) in view of Burchard et al. (U.S. Patent 6,171,794 B1) (January 9, 2001).

Some et al teach a process for detecting a complementary DNA fragment which comprises the steps of:

a) bringing single-stranded sample DNA fragments having a radioactive label in a liquid phase into contact with a group of DNA, so that the complementary DNA fragments are fixed by hybridization to the area in which the group is fixed (Column 7, lines 18-38);

b) removing unfixed sample DNA fragments from the hybridized DNA (Column 7, lines 38-43).

C) keeping the hybridized DNA in contact with a radiation image storage panel containing a stimulable phosphor in areas corresponding to the areas on which groups of DNAs are hybridized, so that the corresponding areas of the stimulable phosphor sheet can absorb and store radiation energy of the radioactive label coming from the fixed DNA fragments through the openings (Figures 1 and 8 and Column 7, lines 43-50);

d) irradiating the radiation image storage panel with a stimulating light, so that the image storage panel releases a stimulated emission from the area in which the radiation energy is stored (Figures 1 and 8 and Column 7, lines 51-67 and Column 8, lines 24-28);

e) detecting the stimulated emission photoelectrically to obtain a series of electric signals (Figures 1 and 8 and Column 8, lines 1-23 and 29-52);

f) processing the electric signals to locate the area in which the complementary DNA fragments are fixed (Figure 6 and Column 12, lines 21-67).

Some et al teach a process, in which the spacer sheet is made of non radiation-transmitting material (Column 8, lines 13-23 and Figures 1 and 8, light guiding sheet in this case)

Some et al teach a process, in which the irradiation image storage panel is irradiated with a stimulating light after it is separated from the DNA microarray (Figures 1 and 8 and Column 7, lines 51-67 and Column 8, lines 24-28).

Some et al do not teach a process, which comprises a DNA micro-array having a support and at least two defined areas in each of which a group of probe compounds selected from DNA molecules or DNA fragments.

Burchard et al. teach a process, which comprises a DNA micro-array having a support and at least two defined areas in each of which a group of probe compounds selected from DNA molecules or DNA fragments are fixed (Abstract, Column 20, line 7 to Column 23, line 17, and Table III and Figure 4 and Examples).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a DNA micro-array having a support and at least two defined areas in each of which a group of probe compounds selected from DNA molecules or DNA fragments are fixed of Burchard et al. into the DNA image forming method of Some et al. since Burchard et al. state, "The present invention provides methods for distinguishing the fractions of polynucleotide sequences which hybridizes to any given probe, including probes on microarrays such as those described herein. In particular, the present invention enables users to identify the fraction of sequences which are perfectly complementary to a probe, thereby correcting for effects of cross hybridization in a hybridization assay (Abstract, first two sentences)." By employing scientific reasoning, an ordinary artisan would have combined and substituted a DNA micro-array having a support and at least two defined areas in each of which a group of probe compounds selected from DNA molecules or DNA fragments are fixed of Burchard et al. into the DNA image forming method of Some et al. to improve the process for

detecting a complementary DNA fragment. An ordinary practitioner would have been motivated to combine and substitute a DNA micro-array having a support and at least two defined areas in each of which a group of probe compounds selected from DNA molecules or DNA fragments are fixed of Burchard et al. into the DNA image forming method of Some et al. in order to achieve the express advantages, as noted by Burchard et al., of an invention that provides methods for distinguishing the fractions of polynucleotide sequences which hybridizes to any given probe, including probes on microarrays such as those described herein and in particular enables users to identify the fraction of sequences which are perfectly complementary to a probe, thereby correcting for effects of cross hybridization in a hybridization assay.

Applicant's arguments with respect to all pending claims have been considered but are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that none of the references teaches spacer sheet having openings. This

argument is not persuasive. Some et al clearly teaches stimulable phosphor sheet, which can absorb and store radiation energy of the radioactive label coming from the fixed DNA fragments through the openings (Figures 1 and 8 and Column 7, lines 43-50).

Applicant then argues the 103 rejection is improper because it lacks a reasonable expectation of success.

With regard to the " lacks a reasonable expectation of success." argument, The MPEP 2143.02 states, "Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. In re Rinehart , 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also Amgen, Inc. v. Chugai Pharmaceutical Co ., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied , 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success. 18 USPQ2d at 1022, 1023.); In re O'Farrell , 853 F.2d 894, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.)."

There is no evidence of record submitted by applicant demonstrating the absence of a reasonable expectation of success. There is evidence in the Some et al. reference of the enabling methodology, the suggestion to modify the prior art, and evidence that a number of different electric signals were processed to locate the area in which the complementary DNA fragments are fixed and hybridization of complementary nucleic acids were actually experimentally studied and found to be functional (Figure 6 and Column 12, lines 21-67) . This evidence of functionality trumps the attorney arguments, which argues that Some et al. reference is an invitation to research, since Some et al. steps beyond research and shows the functional product.

Therefore, all the rejections made in the last office action are hereby properly maintained.

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